



U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

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Natural Guidance, LLC 7/15/11



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Florida District
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Maitland, Florida 32751
Telephone: 407-475-4700
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**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER FLA-11-31

July 15, 2011

Mr. Mitchell A. Propster
Owner
Natural Guidance, LLC
Ancient Naturals, LLC
1000 N. Maitland Ave.
Maitland, FL 32751

Dear Mr. Propster:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your websites www.naturalguidance.com¹ and www.salba.com², as recently as July 2011, and has determined that your Salba® brand products are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on your website establish that the products are drugs because they are intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans. The marketing of the products with these claims violates the Act. You may find the Act and its implementing regulations through links on FDA's home page at www.fda.gov³.

Some examples of claims taken from your website at www.naturalguidance.com⁴, include:

From your homepage under "Natural Product of the Week - Salba Whole Seed Super-grain - 16oz" after clicking on "More Info":

Salba Whole Seed Super-Grain - 16 oz.

"The Benefits of Using Salba Include: ...

- Prevents Blood Sugar Imbalance"

From each product's webpage:

Salba Whole Food Bars (Cranberry Nut, Mixed Berry, and Tropical Fruit)

"Here are the benefits: ...

- Prevents Blood Sugar Imbalance"

Some examples of claims on your website www.salba.com⁵, include the following:

From your "About Us" webpage:

"Salba ... is in the field of management of diabetes specifically with Salba, and methods of use in these seeds in lowering blood pressure, blood glucose and post-prandial glycemia."

From your homepage after clicking on "Products" and then selecting each particular product:

Salba Whole Food Bars (Cranberry Nut, Mixed Berry, and Tropical Fruit)

"Benefits of Using Salba: ...

- Prevents Blood Sugar Imbalance"

From your "Testimonials" webpage:

- "As a nutritional biochemist, I am always looking for new whole foods that my clients can incorporate into their diet.... [I]t (Salba) seems to help with low level depression"
- "My doctor has told me that I need a new heart After a few days of taking Salba, I noticed feeling much more energy.... My cardiologist

... is amazed at the complete transformation in my health."

- "Diabetes Under Control ... I have been a diabetic for ten years. My glucose levels have been higher than my doctor and I would like[,] I read about the effectiveness of salba for glucose control I have taken salba gels for six months or so - my glucose is back under control I feel great and less problems with my allergies."
- "Blood Glucose Down 20 Points!"
- "Salba Helps My Hypoglycemia and IBS"
- "I began using Salba last Thursday (Oct. 20th). I have Celiac Disease and was having trouble internally and run into complications at times where I needed to take a laxative I noticed an improvement within two days."
- "Salba is Working Better than My Prescriptions!! I have been on Salba for about four months now. I have type 2 diabetes and was diagnosed about six years ago. I am on a maximum dose of Metformin and two shots of 10 mcg of Byetta. My blood sugar was still in the 160 - 210 range ... I started mixing 2-3 tablespoons of Salba with oatmeal in the morning ... my blood sugar is between 94 - 114."
- "My Arthritis is Gone! ... I have taken 2 Tbs. (Salba) daily for the last 6 weeks. The arthritis pain in my knees is completely gone!"

From your webpage titled "Salba - A Superior Source of Omega-3s" at www.salba.com/superior_source⁶:

- "Omega-3s Benefits ...
- Child Depression
 - Breast, Colon, and Prostate Cancer
 - Coronary Heart Disease
 - Diabetes management
 - Cardiovascular Heart Disease"

Your Salba® brand products are not generally recognized as safe and effective for the above referenced uses and therefore, the products are new drugs as defined in section 201(p) of the Act [21 U.S.C. § 321(p)]. Under section 505(a) of the Act [21 U.S.C. § 355(a)], a new drug may not be legally marketed in the U.S. without an approved New Drug Application (NDA). FDA approves new drugs on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Furthermore, because your Salba® brand products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; adequate directions for use cannot be written so that a layperson can use these products safely for their intended uses. Thus, your products are also misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352 (f)(1)] in that the labeling for these drugs fails to bear adequate directions for use.

Misbranded Products

Even if your Salba products were not unapproved new drugs, your Salba Whole Seed Super-grain - 16 oz., Salba Ground Seed-9.5 oz., Salba Seed Oil (12oz), Salba Seed Oil Softgels, and Salba Whole Food Bars (Cranberry Nut, Mixed Berry, and Tropical Fruit) would be misbranded under section 403 of the Act [21 U.S.C. 343] because their labeling includes unauthorized nutrient content claims. A claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with an FDA regulation authorizing the use of such a claim. Characterizing the level of a nutrient in food labeling of a product without complying with specific requirements pertaining to nutrient content claims for that nutrient misbrands the product under section 403(r)(1)(A) of the Act.

1. Nutrient content claims that use the defined terms "rich in," "high," or "excellent source of" may be used in the labeling of a food only if the food contains 20 percent or more of the daily value (DV) of that nutrient per reference amount customarily consumed (RACC), as required by 21 CFR 101.54(b)(1). Such claims may not be made about a nutrient for which there is no established DV.

However, your website, www.naturalguidance.com⁷, includes such a claim for specific nutrients even though the food does not contain 20 percent or more of the DV per RACC of these nutrients, in accordance with 21 CFR 101.54(b)(1):

Salba Whole Food Bars (Tropical Fruit, Cranberry Nut, and Mixed Berry)

"[R]ichest sources of ... magnesium, calcium, iron ...

2. Although various nutrient content claims for ALA, DHA, and EPA omega-3 fatty acids have been statutorily authorized through the notification procedure in section 403(r)(3)(C) of the Act [21 U.S.C. § 343(r)(3)(C)], the claims for Omega-3 on your websites do not meet the requirements for any of these claims. Specifically, among other requirements, the claims authorized under the notification procedure must specify whether the claim is referring to ALA, DHA, or EPA omega-3 fatty acids.¹

The following are examples of unauthorized Omega-3 claims on your website, www.salba.com⁸, which can be found on each product's webpage: Salba Seed Oil (12 oz.) and Salba Seed Oil Softgels (90 ct.)

- "[N]ature's richest source of Omega-3s."

Salba Whole Food Bars (Tropical Fruit Cranberry Nut, and Mixed Berry)

- "Salba - nature's richest plant-based source of Omega-3s..."

In addition, the following are examples of unauthorized Omega-3 claims on your website, www.naturalguidance.com⁹, which can be found on each product's webpage:

Salba Whole Food Bars (Tropical Fruit, Cranberry Nut, and Mixed Berry)

- "Salba is nature's richest vegetarian source of ... omega-3s."

Salba Ground Seed - 9.5 oz. and Salba Whole Seed Super-Grain - 16 oz.

- "Richest Source of Omega-3s ... In Nature."

3. Nutrient content claims using the term "antioxidant" must comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, an RDI must have been established for each of the nutrients that are the subject of the claim, and these nutrients must have recognized antioxidant activity. The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act.

However, your websites include "antioxidant claims" that fail to include the names of the nutrients that are the subject of the claim nor do they provide the names of the nutrients with recognized antioxidant activity in accordance with 21 CFR 101.54(g)(2) and (g)(4).

The following are examples of unauthorized nutrient content claims on your website, www.naturalguidance.com¹⁰, that use the term "antioxidant" which can be found on each product's webpage:

Salba Whole Seed Super-Grain - 16 oz. and Salba Whole Food Bars (Cranberry Nut, Mixed Berry, Tropical Fruit)

- "30% More Antioxidants than Blueberries"

Another example of an antioxidant claim on your website, www.salba.com¹¹, which can be found on the product's webpage: Salba Ground Seed – 9.5 oz.

- "With an arsenal of quality nutrients – Magnesium, Protein, Calcium, Antioxidants, Potassium, Iron, and Folate ..."

Establishment Registration

The Food and Drug Administration has determined that your facilities are subject to the registration requirement in Section 415 of the Act [21 U.S.C. § 350d] and our implementing regulation at 21 CFR Part 1, Subpart H. The failure to register a facility as required is a prohibited act under Section 301(dd) of the Act [21 U.S.C. § 331(dd)]. Our records indicate that, to date, your facility, Natural Guidance LLC, has not been registered with FDA, and that you have failed to update and revise the registration from your previous business, Core Naturals LLC, to Ancient Naturals, LLC.

As the owner, operator, or agent in charge of your facility you should register your facilities with FDA immediately. Registration may be accomplished on-line at <http://www.access.fda.gov>¹². We strongly encourage the use of electronic registration because it will result in an automatic confirmation of registration and automatic issuance of a registration number.

The violations mentioned above are not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. You should take prompt action to correct the violations described above and prevent their further recurrence. Failure to promptly correct these violations may result in legal action, without further notice, including, but not limited to, seizure and/or injunction.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct the violations noted above. You should include in your response, documentation and any other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

Please send your reply to the Food and Drug Administration, Attention: Carla A. Norris, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751. If you have questions regarding any issues in this letter, please contact Ms. Norris at (407) 475-4730.

Sincerely,

/s/

Emma R. Singleton
Director, Florida District

¹ FDA issued a proposed rule (72 FR 66103, November 27, 2007) to prohibit some of these nutrient content claims for omega-3 fatty acids.

Links on this page:

1. <http://www.naturalguidance.com>
2. <http://www.salba.com>
3. <http://www.fda.gov>
4. <http://www.naturalguidance.com>
5. <http://www.salba.com>
6. http://www.salba.com/superior_source
7. <http://www.naturalguidance.com>
8. <http://www.salba.com>
9. <http://www.naturalguidance.com>
10. <http://www.naturalguidance.com>
11. <http://www.salba.com>
12. <http://www.access.fda.gov>

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